

MGF-400105
Bemotrizinol (BEMT)

3.2.P.5.4 Batch analyses

The batch analyses will be performed for the Water-in-oil (W/O) emulsion (SU-E-101413-89).

Table 1 in section 3.2.P.5.4: batch analyses result

Test	Specification	Result 001	Result 22017OEV	Result 22018OEV
Physical appearance	Milky	compliant	compliant	compliant
Color	White to off-white	compliant	compliant	compliant
Smell	No smell to characteristic	compliant	compliant	compliant
Viscosity	10'000 – 20'000 cps	compliant	compliant	compliant
Microscope appearance	No phase separation, no crystal formation	compliant	compliant	compliant
Identity of bemotrizinol	Retention time of bemotrizinol peak in the chromatogram corresponds to that of the standard preparation as been shown in the assay.	compliant	compliant	compliant
Assay of bemotrizinol	6.0% (w/w) +/- 0.18% (w/w)	5.92 %	5.92 %	6.00 %
Microbial limit test TAMC TYMC Pseudomonas aeruginosa Staphylococcus aureus Candida albicans Escherichia Coli	NMT 10 CFU/g NMT 10 CFU/g Absent in 1g Absent in 1g Absent in 1g Absent in 1g	compliant	compliant	compliant